Claims

1. A medicinal oral preparation for colon delivery comprising a core containing a pharmacologically active component and, covering the core, an inner layer containing one or more cationic polymers and an outer layer containing one or more anionic polymers, the preparation being designed so that, in a disintegration test comprising vertical movement for 2 hours in a first solution of pH 1.2, subsequent vertical movement for 2 hours in a second solution of pH 7.4, and final vertical movement in a third solution of pH 6.4, the average disintegration initiation time and the average disintegration completion time each fall within a period from 35 min to 130 min after starting the vertical movement in the third solution.

2. The medicinal oral preparation for colon delivery according to Claim 1, wherein the preparation is designed so that the average disintegration initiation time is 35 min to 115 min and the average disintegration completion time is 50 min to 130 min after starting the vertical movement in the third solution.

3. The medicinal oral preparation for colon delivery according to either Claim 1 or 2, wherein the core is a solid preparation or a capsule.

4. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 3, wherein the cationic polymer dissolves or swells at a pH of 6.5 or lower, and the anionic polymer dissolves at a pH of 6.5 or higher.

5. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 4, wherein the cationic polymer is one selected from the group consisting of a copolymer of methyl methacrylate, butyl methacrylate, and dimethylaminoethyl methacrylate (aminoalkyl methacrylate copolymer) and polyvinyl acetal diethylaminoacetate, and the weight of the inner layer relative to the core is 5 to 15 wt %.

6. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 5, wherein the anionic polymer is one selected from the group consisting of a copolymer of methacrylic acid and methyl methacrylate, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, carboxymethylethyl cellulose, cellulose acetate phthalate, and cellulose acetate succinate, and the weight of the outer layer relative to the core is 5 to 15 wt %.

7. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 6, wherein the core contains one or more types selected from the group consisting of a disintegrating agent, a pH adjusting agent, a thickening agent, a binder, and a saccharide.

8. The medicinal oral preparation for colon delivery according to Claim 7, wherein the core contains as the disintegrating agent 3 to 15 wt % of one or more types selected from the group consisting of crospovidone, pregelatinized starch, sodium carboxymethyl starch, carmellose, calcium carmellose, sodium carmellose, powdered agar, sodium croscarmellose, low-substituted hydroxypropyl

cellulose, starch, dextrin, hydroxyethylmethyl cellulose, carboxymethyl cellulose, hydroxypropyl starch, Macrogol, and mannitol.

9. The medicinal oral preparation for colon delivery according to Claim 7, wherein the core contains as the pH adjusting agent 5 to 20 wt % of a weakly acidic amino acid comprising one or more types selected from the group consisting of phenylalanine, alanine, aspartic acid, glutamine, glutamic acid, methionine, glycine, and cysteine.

10. The medicinal oral preparation for colon delivery according to Claim 7, wherein the core contains as the pH adjusting agent 5 to 20 wt % of a basic amino acid comprising one or more types selected from the group consisting of arginine, lysine, and histidine.

11. The medicinal oral preparation for colon delivery according to Claim 7, wherein the core contains as the pH adjusting agent 0.1 to 3 wt % of an organic acid comprising one or more types selected from the group consisting of citric acid, fumaric acid, succinic acid, and tartaric acid.

12. The medicinal oral preparation for colon delivery according to Claim 7, wherein the core contains as the thickening agent 5 to 30 wt % of one or more types selected from the group consisting of hydroxypropyl cellulose, guar gum, hydroxypropylmethyl cellulose, polyvinyl pyrrolidone, xanthan gum, and gum arabic.

13. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 12, wherein the pharmacologically active component is selected from the group consisting of a peptide, a protein, an antisense drug, an

anti-inflammatory drug, an antitumor drug, an antibiotic, a chemotherapeutic drug, a probiotic, an antidiarrheal drug, a purgative, and a laxative.

14. The medicinal oral preparation for colon delivery according to any one of Claims 1 to 13, wherein the core has a diameter of 5 to 8 mm and a thickness of 3 to 6 mm.

15. A medicinal oral preparation for treating colon cancer comprising a core containing 10 to 70 wt % of fluorouracil and, covering the core, an inner layer containing one or more cationic polymers and an outer layer containing one or more anionic polymers.

16. The medicinal oral preparation for treating colon cancer according to Claim 15, wherein the preparation is designed so that, in a disintegration test comprising vertical movement for 2 hours in a first solution of pH 1.2, subsequent vertical movement for 2 hours in a second solution of pH 7.4, and final vertical movement in a third solution of pH 6.4, the average disintegration initiation time and the average disintegration completion time each fall within a period from 35 min to 130 min after starting the vertical movement in the third solution.

17. The medicinal oral preparation for treating colon cancer according to Claim 16, wherein the preparation is designed so that the average disintegration initiation time is 35 min to 115 min and the average disintegration completion time is 50 min to 130 min after starting the vertical movement in the third solution.

18. The medicinal oral preparation for treating colon cancer according to any one of Claims 15 to 17, wherein the

core contains one or more types selected from the group consisting of a binder, a disintegrating agent, and a saccharide.

19. The medicinal oral preparation for treating colon cancer according to Claim 18, wherein the core contains 5 to 40 wt % of the binder, and the mixing ratio of fluorouracil and the binder is 1:0.5 to 1:5.

20. The medicinal oral preparation for treating colon cancer according to either Claim 18 or 19, wherein the binder is one or more types selected from the group consisting of crystalline cellulose, gum arabic, sodium alginate, ethyl cellulose, agar, a carboxyvinyl polymer, carmellose, gelatin, low-substituted hydroxypropyl cellulose, starch, dextrin, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, pectin, polyvinyl pyrrolidone, Macrogol, and methyl cellulose.

21. The medicinal oral preparation for treating colon cancer according to Claim 18, wherein the core contains 2 to 15 wt % of the disintegrating agent, and the mixing ratio of fluorouracil and the disintegrating agent is 1:0.05 to 1:1.

22. The medicinal oral preparation for treating colon cancer according to either Claim 18 or 21, wherein the disintegrating agent is one or more types selected from the group consisting of crospovidone, pregelatinized starch, sodium carboxymethyl starch, carmellose, calcium carmellose, sodium carmellose, powdered agar, sodium croscarmellose, low-substituted hydroxypropyl cellulose, starch, dextrin, hydroxyethylmethyl cellulose, hydroxypropyl starch, Macrogol, and mannitol.

23. The medicinal oral preparation for treating colon cancer according to Claim 18, wherein the core contains 20 to 60 wt % of the saccharide.

24. The medicinal oral preparation for treating colon cancer according to either Claim 18 or 23, wherein the saccharide is one or more types selected from the group consisting of monosaccharides and disaccharides of lactose, fructose, sucrose, glucose, xylitol, maltose, mannitol, and sorbitol, polysaccharides of cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, ethyl cellulose, starch, dextrin, dextran, pectin, and pullulan, and derivatives thereof.

25. A medicinal oral preparation for treating colitis comprising a core containing 0.5 to 10 wt % of budesonide and, covering the core, an inner layer containing one or more cationic polymers and an outer layer containing one or more anionic polymers.

26. The medicinal oral preparation for treating colitis according to Claim 25, wherein the preparation is designed so that, in a disintegration test comprising vertical movement for 2 hours in a first solution of pH 1.2, subsequent vertical movement for 2 hours in a second solution of pH 7.4, and final vertical movement in a third solution of pH 6.4, the average disintegration initiation time and the average disintegration completion time each fall within a period from 35 min to 130 min after starting the vertical movement in the third solution.

27. The medicinal oral preparation for treating colitis according to Claim 26, wherein the preparation is designed so

that the average disintegration initiation time is 35 min to 115 min and the average disintegration completion time is 50 min to 130 min after starting the vertical movement in the third solution.

28. The medicinal oral preparation for treating colitis according to any one of Claims 25 to 27, wherein the core contains one or more types selected from the group consisting of a binder, a disintegrating agent, and a saccharide.

29. The medicinal oral preparation for treating colitis according to Claim 28, wherein the core contains 5 to 40 wt % of the binder, and the mixing ratio of budesonide and the binder is 1:10 to 1:30.

30. The medicinal oral preparation for treating colitis according to either Claim 28 or 29, wherein the binder is one or more types selected from the group consisting of crystalline cellulose, gum arabic, sodium alginate, ethyl cellulose, agar, a carboxyvinyl polymer, carmellose, gelatin, low-substituted hydroxypropyl cellulose, starch, dextrin, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, pectin, polyvinyl pyrrolidone, Macrogol, and methyl cellulose.

31. The medicinal oral preparation for treating colitis according to Claim 28, wherein the core contains 2 to 15 wt % of the disintegrating agent, and the mixing ratio of budesonide and the disintegrating agent is 1:2 to 1:10.

32. The medicinal oral preparation for treating colitis according to either Claim 28 or 31, wherein the disintegrating agent is one or more types selected from the group consisting of crospovidone, pregelatinized starch, sodium carboxymethyl starch, carmellose, calcium carmellose, sodium carmellose,

powdered agar, sodium croscarmellose, low-substituted hydroxypropyl cellulose, starch, dextrin, hydroxyethylmethyl cellulose, hydroxypropyl starch, Macrogol, and mannitol.

33. The medicinal oral preparation for treating colitis according to Claim 32, wherein the disintegrating agents are crospovidone and low-substituted hydroxypropyl cellulose.

34. The medicinal oral preparation for treating colitis according to Claim 33, wherein the mixing ratio of crospovidone and low-substituted hydroxypropyl cellulose is 1:2.5 to 1:10.

35. The medicinal oral preparation for treating colitis according to Claim 28, wherein the core contains 40 to 80 wt % of a saccharide.

36. The medicinal oral preparation for treating colitis according to either Claim 28 or 35, wherein the saccharide is one or more types selected from the group consisting of monosaccharides and disaccharides of lactose, fructose, sucrose, glucose, xylitol, maltose, mannitol, and sorbitol, polysaccharides of cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, ethyl cellulose, starch, dextrin, dextran, pectin, and pullulan, and derivatives thereof.